

## **REMARKS/ARGUMENTS**

### **Information Disclosure Statements**

Applicant would like to thank the Examiner for his explanation for lining through references A4, A44, A46, B7 and B13 cited in the Information Disclosure Statement (IDS) filed on March 16, 2005.

### **Description of amendments**

In the specification, numerous paragraphs have been amended to correct editorial issues. In addition, the paragraph in which the reference character 120 was used to refer to a metallic surface has been amended to use reference character 110 to refer to a metallic surface in this paragraph.

Claims 6 - 29 and 47 - 49 are pending in the application. Claims 9 - 21 and 24 - 26 have been withdrawn. Claims 30 - 46 have been cancelled. Claims 6 - 8, 22, 23, 27 - 29 and 47 - 49 have been rejected.

Claims 47 - 49 were added in the applicant's response mailed on September 10, 2007 in response to the Office Action mailed April 9, 2007. Applicant states that these claims belong to the restricted Group I cited in the September 19, 2005 restriction requirement as these claims are for medical devices, not methods. In addition, claims 47 - 49 also belong to elected species A (Figure 4) from the election requirement mailed on September 19, 2005, and species B (metal) from the election requirement mailed on May 31, 2006.

Claims 7, 27, 48, and 49 are amended.

Withdrawn claims 13, 18, 21, and 26 are amended.

No new matter is introduced by this amendment.

Amendment to claim 7 is supported by at least page 2, lines 19 - 20 of the originally filed specification.

Amendment to claim 27 is supported by at least page 2, lines 13 - 15 of the originally filed specification and Figure 4.

Reconsideration and reexamination are respectfully requested in view of the foregoing claim amendments and the remarks presented below.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 48 and 49 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48 and 49 are amended. The reference to “the stent” has been removed and replaced with “the medical device.” As “the medical device” has proper antecedent basis, applicant asserts that claims 48 and 49 are no longer indefinite.

Applicant respectfully requests that the Examiner withdraw the 35 USC 112, second paragraph rejection of claims 48 and 49.

Rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 6, 22, 23, 27, and 47 - 49 under 35 U.S.C. §103(a) as being unpatentable over Serbousek et al., United States Patent 5,916,269 ("Serbousek") in view of Shoher et al., United States Patent 4,434,211 ("Shoher"), and Koch et al., United States Patent 5,181,926 ("Koch").

Applicant respectfully traverses the Examiner's rejection for at least the following reasons.

First, the three references do not disclose all of the features of applicant's independent claims 6 and 27. In particular, both claims 6 and 27 recite a ceramic component with regions (or sides) of different porosity. The Examiner states that this feature is not disclosed in Serbousek. Applicant asserts that this feature also is not disclosed in either Shoher or Koch. Thus, the references do not recite each element of claims 6 and 27.

As noted in the 8<sup>th</sup> Edition, 6<sup>th</sup> Revision of the MPEP, section 2141(III), "[t]he 'mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness' *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976)." However, "[o]ffice personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art" (MPEP 2141(III)). Moreover, as further noted in MPEP 2141 (III), to establish a *prima facie case* of obviousness, the following is required:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82USPQ 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained by mere conclusory statements;

instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at \_\_\_\_, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

Applicant asserts that the Examiner has not established a *prima facie case* of obviousness for the Examiner has provided no explanation of why the “inserts [that] are ceramic having different porous regions” (Office Action mailed 29 November 2007, application 10/623,908) are obvious. Thus, independent claims 6 and 27 are patentable over the combination of Serbousek in view of Koch and further in view of Shoher. As claims 22, 23, 47, and 49 depend from claim 6, and claim 48 depends from claim 27, these dependent claims are patentably allowable for at least the same reasons that claims 6 and 27 are allowable.

In addition, applicant asserts that the combination of references is improper. Specifically, the Examiner states:

It would have been obvious to one of ordinary skill in the art to use ceramic inserts as taught by Koch et al. to modify the surface of the medical device of Serbousek et al. such that it provides a more wear resistant surface and use the bonding method of Shoher et al. to secure the ceramic component in the surface.

However, as noted in Serbousek, “The present invention is based upon the discovery that a bearing component having an articular face, interrupted by either recesses or protrusions, minimizes production of joint debris created by the interaction between the face and an accompanying joint face articulation member.” Thus, one of ordinary skill in the art, upon reading the disclosure of Serbousek would NOT be lead to place ceramic inserts into the recesses of the medical device of Serbousek because Serbousek teaches that the decreased wear is a result of reduced surface area of contact.

The ceramic inserts of Koch are designed to “facilitate the ‘adjustment’ or ‘adaptation’ of the support members to the bearing surfaces of the hard member” (column 2, lines 10 – 13). In particular, there is no mention that these inserts are physically attached to the softer second member. There is limited contact area between the inserts and the second member since the surface of each are “dished” (convex) to allow for movement. As noted in Koch, the invention is designed such that “the relative movements of the support members 3 in the acetabulum 1 are facilitated so that the sliding surfaces 4 of the support members 3 always about the femur head prosthesis 11 with the largest possible surface” (column 3, lines 3 - 7). As a result, attachment with the bonding method of Shoher is not only not contemplated by the invention of Koch, but also would likely impair the ability of the inserts to freely move in the recesses. Impairment of the ability of the inserts to move would likely impact the ability of the inserts to reduce wear and abrasion. Thus, Koch essentially teaches away from attaching the inserts to the second member.

In summary, for all of the reasons outlined above, applicant asserts that claims 6, 22, 23, 27, and 47 – 49 are patentable over the references cited. Applicant respectfully requests the removal of the rejection, and allowance of claims 6, 22, 23, 27, and 47 - 49.

The Examiner has rejected claims 7, 8, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Serbousek in view of Shoher and Koch in view of Alt, United States Patent 6,099,561 (“Alt”).

Applicant respectfully traverses the Examiner’s rejection for at least the following reasons.

First, as indicated above, claims 6 and 27 are patentable over the combination of Serbousek in view of Koch, and further in view of Shoher. Alt does not cure the deficiencies of these references with respect to claims 6 and 27. Accordingly, claims 6 and 27 are patentably allowable over all four references. Claims 7 and 8 depend from claim 6, and claims 28 and 29 depend from claim 27, and are patentable for at least the same reason that independent claims 6 and 27 are patentable.

Second, without agreeing with the Examiner's assertions with respect to Lambert, United States Patent 5,900,246, applicant asserts that the Examiner's combination of references is improper.

The Examiner states:

It would have been an obvious expedient to one of ordinary skill in the art to incorporate an anti-inflammatory drug in the porous ceramic as taught by Alt with the implantable device of Serbousek as modified by Koch and Shoher because the body's defense mechanisms and thus the drug would aid in reducing inflammation at the implantation site.

However, Serbousek discloses recesses in an articular face that is intended to be mated with a corresponding joint face (essentially a ball in a socket). Assuming, arguendo, that one of ordinary skill in the art would place the inserts of Koch into these recesses, one of ordinary skill in the art would not be lead to use this location for incorporating a drug in the prothesis. The ceramic inserts would be directly against the joint face of the corresponding joint, and not directly adjacent to tissue. Thus, drug would be hindered from reaching the tissue.

Moreover, Koch teaches away from the combination of Alt and Koch. Alt discloses a rough outer surface (column 7, line 5) of the ceramic to allow for the incorporation of a drug into

the interstices. However, Koch teaches that the “hard support members [ceramic inserts] act as low-abrasion or practically abrasion free-slide bearing surfaces when the joint employing the bone implant is subjected to a load” (column 1, lines 63 - 65). It is applicant’s position that the “abrasion free-slide bearing surfaces” of the inserts of Koch teach away from the rough surface of Alt.

In summary, applicant asserts claims 7, 8, 28, and 29 are patentably allowable over the references cited by the Examiner. Applicant respectfully requests that the Examiner remove the rejection of claims 7, 8, 28, and 29, and allow these claims.

### **CONCLUSION**

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicant respectfully requests the allowance of pending claims 6 - 8, 22, 23, 27 - 29, and 47 - 49 that have been examined. No new matter has been added, and all cancellations have been made merely to expedite prosecution of the application. Accordingly, applicant reserves the right to continue pursuing previously presented arguments in any divisional, continuation, or continuation-in-part applications. In particular, applicant reserves the right to file a divisional application on unelected Group II, claims 30 - 46 from the September 19, 2005 restriction requirement which have been cancelled.

As applicant respectfully submits that the pending claims are in condition for allowance, applicant requests rejoinder of withdrawn claims 9 - 21, and 24 - 26. MPEP § 821.04 recites the following:

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.

Claims 9 - 21 and 24 - 26 depend from, directly or indirectly, claim 6. Therefore, with respect to withdrawn claims 9 - 21 and 24 - 26, applicant respectfully requests that the Examiner rejoin these claims and subsequently examine these claims on the merits. Specifically, applicant requests that the Examiner rejoin the above mentioned claims, and to examine all pending claims from Group I with respect to unelected species B – H from the September 19, 2005 election requirement, and unelected species A, C, and D from the May 31, 2006 election requirement.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the examiner to charge any fees that may be required, or credit of any overpayment to be made, to **Deposit Account No. 07-1850.**

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.



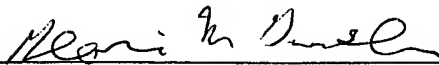
Respectfully submitted,

Date: February 19, 2008

---

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0397 (direct)  
Telephone (415) 954-0200

---

  
Gloria Gusler, Ph.D.  
Attorney for Applicant  
Reg. No. 50,282